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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,455	04/19/2002	Tahmina Mujtaba	UT-0033	1827

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EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,455	MUJTABA ET AL.	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2006, has been entered.

Claim 5 is presented for consideration on the merits.

Amendment of January 30, 2006

The amendments and remarks filed January 30, 2006 are acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for stem cells capable of contributing to all cell lineages from a ES-D3 cell line grown under specifically controlled condition, does not reasonably provide enablement for any and all cell lines under any given set of conditions. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to practice and carry out the invention commensurate in scope with these claims. The instantly filed specification discloses that the ES-D3 cell line has been shown to be able to contribute to all cell lineages, but only when grown under controlled conditions. Therefore, it is clear from Applicants own specification that not all cell lines under any given set of conditions can produce stem lines capable of contributing to all cell lineages. The scope of the claim is too broad, therefore, for the enabling disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 does not appear to be supported by the specification for the language "from a cell line which contributes to all cell lineages" because the metes and bounds of the claim can not be determined. The specification does not provide sufficient support for the language as described in the claim and thus, the language renders the claim vague and indefinite as to what cell lines are intended to contrubute to all cell lineages, and further, what are these cell lineages? The claim is too unclear and is not well defined in the specification.

Claim Rejections - 35 USC § 103

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al (March 1998, BF citation on enclosed PTO-1449 Form) in view of Rao et al (US Pat No. 6,361,996).

Claim 5 is drawn to a method for isolating a pure population of mouse glial-restricted precursor cells derived from mouse embryonic stem cells by incubating thos from a cell line which contributes to all cell lineages, under differentiation-inducing conditions and isolating the mouse glial-restricted precursor cells via immunoselecting A2B5+ immunoreactive cells from differentiated cells.

Rao et al (1998) teach isolated glial restricted precursor cells from spinal cords of rats using procedures in vitro A2B5+ immunoreactivity. See the abstract. Also, after the abstract, at col. 1, of page 3996, lines 13-14, the best defined glial prescursor cell is the A2B5+ progenitor cells (stem cells) isolated from rat embryos. Spinal cord tissue is used which comprises the neural tube.

Further, the best defined glial precursor cell is the A2B5 progenitor cell which is initially isolated from embryonic stem cells of the rat. In addition, steps of incubating stem cells under differentiation-inducing conditions and isolating a pure population of glial-restricted precursor cells by immunoslecting A1B5-immunoreactive cells from the differentiated cells are disclosed, note page 3996, column 2, Materials and Methods and continued onto page 3997, column 1, lines 3-6. Note that greater than 98% purity is obtained using A2B5 immunoselection technique.

Rao et al (US Pat '996) teach the central nervous system (CNS) contains precursor cells with restricted differentiation potentials and the isolation, characterization and use of stem cells from the central nervous systems. Note column 1, lines 45-46. Also the steps of incubating and isolating pure population of glial-restricted cells by immunoselecting A2B5-immunoreactive cells are disclosed, see column 5, lines 1-10 and column 13, line 15. As a whole they desire to isolate populations of mammalian embryonic stem cells and lineage restricted glial precursor cells, see column 3, lines 40-44. Furthermore, they use stem cells derived from the rat but they are not limited to stem cells from the rat, and may choose to use mammalian stem cells from a variety of species, note column 6, lines 29-34. Also at column 15, lines 40-41, mouse is another rodent besides the rat from which they may isolate precursors. Note the abstract and col. 5, lines 40-45 and 63 and col. 6, lines 5-15 and col. 9, example 1. Note also col. 13, lines 55-63, col. 4, lines 40-66, and col. 5, lines 1-25. Further, see col. 9, lines 20-22.

The claims differ from Rao et al in that rats are used and not a mouse to obtain the cells in greater purity.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to isolate the glial restricted precursor cells as disclosed by Rao et al from a mouse because Rao et al ('996) also disclose the mouse to be a source of precursors as well, for carrying out the steps of incubating and isolating via immunoselection in a method for isolating glial restricted precursor cells.

To obtain the cells in an amount of greater purity while using the method steps of obtaining these cells as disclosed by Rao et al. would have been expected to provide successful results. Method for isolating these cells by A2B5+ immunoreactivty is disclosed by both Rao et al. references.

Therefore, to incubate and isolate them would have been expected to yield greater purity because the central nervous system of a rodent is known to have greater than 90% glial cells. It would have been obvious to one of ordinary skill in the art to increase the number of glial restricted cells obtained by the methods of Rao et al in order to enhance the purity of the population because these cells are present in the central nervous system at a level of 90%.

One of skill in the art would have expected successful results for isolating these cells at a greater purity while using the methods of obtaining these cells as disclosed by Rao et al. Using the same procedures as Rao et al and the same class source, rodent, would have been expected to provide a successful yield of pure cells.

Each of the process steps employed by Applicants' claimed methods of isolating the cells are disclosed by Rao et al. Note col. 4-5, lines 40-66 and lines 1-26. In the absence of persuasive evidence to the contrary the claims are rendered prima facie obvious over the cited prior art. The claims are rendered prima facie obvious over the newly applied art reference.

Response to Arguments

Applicant's arguments filed January 30, 2006, have been fully considered but they are not persuasive. The argument that the starting material of the claimed method

from which the mouse glial restricuted precursor (GRP) cells are isolated, namely embryonic stem cells, is different, is noted. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., embryonic stem cells) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

However, while Rao et al (1998) does not teach any other starting material but rat, to select a mouse in place of a rat would have been an obvious modification of the cited prior art because a mouse is desirable because of its small size and due to the desire in the art to maximize efficiency in a lab setting to select a mouse would have been obvious.

Further, the other Rao et al ('996) reference applied clearly teach that such methods of isolating GRP cells is not limited to the rat and even teaches other mammalian sources including the mouse.

Further, both the rat and mouse are mammalian rodents and one of skill in the art would have expected successful results with either of these mammals. To choose embryonic stem cells is taught, or at least suggested, by the cited prior art. Also the argument that the cited prior art does not disclose that any and all cell lineages can be obtained from any cell line is noted, however, Applicants have not proper support for this claim either as noted above. Thus, the rejection is sustained.

The claim fails to be patentably distinguishable over the state of the art discussed above. Therefore, the claim is properly rejected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah K. Ware
PATENT EXAMINER
Deborah K. Ware
June 10, 2006